ARC 7191B

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 13, "Sterile Compounding Practices," Iowa Administrative Code.

This amendment was approved at the July 29, 2008, regular meeting of the Board of Pharmacy.

The proposed amendment clarifies the requirements for a supervising pharmacist to perform in-process checks of compounding functions performed by a nonpharmacist and the requirements for documentation of that verification.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on October 14, 2008. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

This amendment is intended to implement Iowa Code sections 155A.2, 155A.6A, 155A.13, and 155A.33.

The following amendment is proposed.

Amend subrule 13.3(2) as follows:

13.3(2) *In-process checking procedure.* Each pharmacy shall establish a written quality assurance procedure that includes the following in-process checks:

a. Appropriate procedures are followed for measuring, mixing, diluting, purifying, sterilizing, packaging, and labeling of the specific preparation.

b. Packaging selection is appropriate to preserve the sterility and strength of the preparation.

c. ~~All~~ If functions are performed by ~~nonpharmacists are verified by~~ a nonpharmacist, the pharmacist ~~before the preparation is dispensed to the patient~~ shall verify the accuracy of the procedure at each step during the compounding process. Documentation that identifies the individual performing each step of the compounding process and the pharmacist verifying the accuracy of each step of the process shall be maintained and be available for inspection and copying by the board or its representative for at least two years.

d. If an electronic record capable of identifying each component and measurement required in the compounding process is created and utilized, pharmacist verification shall be completed before the preparation is dispensed to the patient. Documentation that identifies the individual performing each step of the compounding process and the pharmacist verifying the accuracy of the compounding process shall be maintained and be available for inspection and copying by the board or its representative for at least two years.